

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

		in the second se		
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,845	04/26/2000	HIDENORI FUNAMIZU	2554-7	5849
75	90 11/13/2003	EXAMINER		
NIXON & VANDERHYE			COLEMAN, BRENDA LIBBY	
1100 NORTH GLEBE ROAD 8TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22201-4714			1624	
•			DATE MAILED: 11/13/2003	19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/485,845

Applicant(s)

FUNAMIZU et al.

Examiner

Brenda Coleman

Art Unit **1624**



Pariod for Repty A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Extension of time may be available under the provisions of 37 CFR 1,138 (a). In no event, however, may a repty be trively filed after SX (ii) MONTHS from the mailing date of this communication If NO pariod for repty is predicted above, the nexternal relatively provided algory and will apply safe of the communication If NO pariod for repty is predicted above, the nexternal relatively provided algory and will expire SK (ii) MONTHS from the mailing date of this communication If NO pariod for repty is applicated above, the nexternal relatively provided algory and will expire SK (iii) MONTHS from the mailing date of the communication, even if finally filled and the communication If NO pariod for repty is application in the mailing date of this communication, even if finally filled and part the mailing date of the communication, even if finally filled and part the mailing date of the communication, even if finally filled and part of the communication and in the communication and the comm	The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
THE MALING DATE OF THIS COMMUNICATION. Extensions of term we be available under the provisces of 2 TGR 1.138 (a). In no event, however, may a raply be timely filed after \$IX (8) MONTHS from the malling date of this communication. If the period for every bearded above in less than thirry (30) days, a raply within the statisticn mailtains of the provision of the provision of the provision of the provision of the communication. If the period for every device the second or provision of the provision of the provision of the communication. Failure to reply within the set or extended parted for reply with by statuta, assess the specification, own of it trively field, may reduce any served patent from adjustment. See 37 CFR 1.704(b). Status This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) Claim(s) 67-76 and 85 Siare withdrawn from consideration. 50 Claim(s) Siare withdrawn from consideration. 51 Claim(s) Siare withdrawn from consideration. 52 Claim(s) Siare withdrawn from consideration. 53 Siare sepected to by the Examiner. 10 The drawing(s) filled on siare on siare a accepted or b) objected to by the Examiner. 11 The proposed drawing correction filled on is/are a accepted or b) disapproved by the Examiner. 12 The optoposed drawing correction filled on is/are a accepted or b) disapproved by the Examiner. 13 The other of copies of the priority documents have been received. 2 Certified copies of the priority documents have been received in Application No. 3 Copies of the certified copies of the priority documents have been received in this Netional Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for domestic priority under 35 U.S.C. \$ 119(a). 14 Motice of Peterserses C		• •					
Intelligence of this communication. If the period for party practical debrow is lace than thirty (30) days, a reply within the stratutory minimum of theiry (30) days will be considered timely, in specified above, the minimum stations period will apply and will agries BX. (8) MONTHS from the making after of the communication. If No period for high is specified above, the minimum stations period will apply and will agries BX. (8) MONTHS from the making date of this communication. If No period for high is specified above, the minimum stations period will apply and will agries BX. (8) MONTHS from the making date of this communication. If No period for high is specified above, the minimum stations period will apply and will apply and will state the making date of this communication. If No period for the specified above, the minimum state of the minimum state of the making and state of the communication. If No period for the specific and state of the minimum state of the minimum state of the minimum state of the minimum state of the communication. If No period for the minimum state of the period will approve the minimum state of the priority documents have been received. If period the minimum state of a claim for domestic priority under 35 U.S.C. § 119(a)-(d) or (f). Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(a)-(d) or 42. Copies of the periority documents have been received. Copies of the certified copies of the priority documents have been received. Copies of the certified species of the priority documents have been received. Copies of the certified species of the priority documents have been received. Copies of the certified species of the priority documents have been received. Copies of the certified species of the priority documents have been received. Copies of the certified	THE MAILING DATE OF THIS COMMUNICATION.						
if No period for reply is specified above. the maximum statutory period will pept yet MI specified to the specified store between period period for replication reply within the set or retarded period for reply with the status of the maniful date of this communication. Fallate to reply within the set or retarded period for reply with the status of the replication is an application in the period from the status. 1	mailing	g date of this communication.					
1)	 If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any 						
2al This action is FINAL. 2b This action is non-final. 3 Since this application is in condition for allowence except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4i) Claim(s) 67-76 and 85	Status						
3 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) Claim(s) 67-76 and 85	1) 💢	Responsive to communication(s) filed on Sep 2, 20)03				
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) Claim(s) 67-76 and 85	2a) 💢	This action is FINAL . 2b) ☐ This act	tion is non-final.				
Claim(s) 67-76 and 85 is/are pending in the application. is/are withdrawn from consideration. is/are withdrawn from consideration. is/are withdrawn from consideration. is/are allowed. is/are allowed. is/are rejected. is/are objected to. is/are objected to. is/are objected to. is/are objected to. objected to. objected to restriction and/or election requirement. Application Papers The specification is objected to by the Examiner. The drawing(s) filled on	3) 🗆						
day of the above, claim(s)	Disposit	tion of Claims					
Sizare allowed. Sizare allowed. Sizare rejected. Sizare rejected. Sizare rejected. Sizare objected to. Sizare objected to press Sizare objected to by the Examiner. Sizare objected to by the Examiner. Sizare objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Sizare objected to by the Examiner. Sizare objected drawings are required in reply to this Office action. Sizare objected by the Examiner. Sizare objected drawings are required in reply to this Office action. Sizare objected by the Examiner. Sizare objected to sizare objected to by the Examiner. Sizare objected to sizare objected to sizare objected to sizare objected objected objected to sizare objected objec	4) 💢	Claim(s) <u>67-76 and 85</u>			is/are pending in the application.		
Sizare allowed. Sizare allowed. Sizare rejected. Sizare rejected. Sizare rejected. Sizare objected to. Sizare objected to press Sizare objected to by the Examiner. Sizare objected to by the Examiner. Sizare objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Sizare objected to by the Examiner. Sizare objected drawings are required in reply to this Office action. Sizare objected by the Examiner. Sizare objected drawings are required in reply to this Office action. Sizare objected by the Examiner. Sizare objected to sizare objected to by the Examiner. Sizare objected to sizare objected to sizare objected to sizare objected objected objected to sizare objected objec	4	a) Of the above, claim(s)			is/are withdrawn from consideration.		
Size							
Claims					·		
Application Papers 9							
Application Papers 9	8) 🗌	Claims	are	subject 1	to restriction and/or election requirement.		
The drawing(s) filed on							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on	9) 🗆	The specification is objected to by the Examiner.					
11) The proposed drawing correction filed on	10)	The drawing(s) filed on is/are	; a) 🗌 accepted	or b)□	objected to by the Examiner.		
11) The proposed drawing correction filed on							
If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(e). 5) Notice of Informal Patent Application (PTC-152)	11) 🗆	The proposed drawing correction filed on	is:	a) 🗆 ap	pproved b) \square disapproved by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17. 2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summery (PTO-413) Paper No(e). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)							
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 5) Notice of Informal Patent Application (PTO-152)	12)	The oath or declaration is objected to by the Exami	iner.				
a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § \$ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)							
1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	a)	a) □ All b) □ Some* c) □ None of:					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § § 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	•	1. Certified copies of the priority documents have been received.					
*See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § § 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	;	2. Certified copies of the priority documents have been received in Application No					
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § § 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	application from the International Bureau (PCT Rule 17.2(a)).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	_						
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)							
Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)							
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)							
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)	_		4) Distancione Sum	PTO	412) Denos No/-)		
					• •		
of of of							

Application/Control Number: 09/485,845 Page 2

Art Unit: 1624

DETAILED ACTION

Claims 67-76 and 85 are pending in the application.

This action is in response to applicant's amendment filed September 2, 2003. Claim 85 was amended.

Response to Amendment

Applicant's arguments filed September 2, 2003 have been fully considered with the following effect:

1. With regards to the rejection as being drawn to an improper Markush group of the last office action, the applicant's stated that "claim 85 has been amended to delete those structures of A_1 which are not within the elected subject matter". However, species claim 67 still contains many species which A_1 is other than those structures within the elected subject matter.

Claim 67 is rejected as being drawn to an improper Markush grouping. For reasons of record and stated above.

- 2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection labeled paragraph 2 maintained in the last office action, which is hereby withdrawn.
- 3. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 6 maintained in the last office action, the applicant's stated that "growth hormone is mentioned on page 28, line 13 of the specification". However, the mere statement of "growth hormone" does

Application/Control Number: 09/485,845 Page 3

Art Unit: 1624

not provide written description for those growth hormones the applicants intend other than those specifically mentioned under growth hormone secretagogues selected from KP-102 (GHRP-2), GHRP-6, Hexarelin and GHRP-1 and growth hormone releasing factor (GRF) selected from IGF-1, IGF-2 and B-HT920.

Claim 69 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

4. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 8 of the last office action, the applicant's stated that "Example Nos. 67 and 68 on page 45 relate to 1,4-dioxo-2,3-dihydro-benzo[1,5]thiazepine and Example No. 172 has the structure: -NH-CH₂-CH(OH)-CH₂-NH-CH₂-CH(OH)-CH₃". However, the definition of A₁ where A₁ is 1,4-dioxo-2,3-dihydro-benzo[1,5]thiazepine in examples 67 and 68 is part of a single species with specific variables, not the description of the genus of formula I. The definition of D where D is -NH-CH₂-CH(OH)-CH₂-NH-CH₂-CH(OH)-CH₃ in example 172 is part of a single species with specific variables, not the description of the genus of formula I. Additionally, recent case law Tronzo v. Biomet 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

Art Unit: 1624

Claim 85 (and claims dependent thereon) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner

Application/Control Number: 09/485,845 Page 5

Art Unit: 1624

can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for OFFICIAL business is 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

> Brenda Coleman Primary Examiner AU 1624

Brenda Coleman

November 11, 2003